# APPENDIX

## Text of Pertinent Sections of the Food, Drug and Cosmetic Act.

Act § 201(p), 21 U.S.C. 321(p)

"(p) The term 'new drug' means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

Act § 301(d); 21 U.S.C. 331(d)

"Sec. 301. The following acts and the causing thereof are hereby prohibited:

* * *

*Text of Pertinent Sections of the Food, Drug and Cosmetic Act.*

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505."

Act § 302(a); 21 U.S.C. 332(a)

"Sec. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies and for other purposes', approved October 15, 1914, as amended (U.S.C. 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (h), (i) and (j)."

Act § 303(a); 21 U.S.C. 333(a)

"Sec. 303. (a) Any person who violates a provision of section 301 (other than a provision referred to in subsection (b) of this section) shall be imprisoned for not more than one year or fined not more than $1,000, or both; except that if any person commits such a violation after a conviction of him under this subsection has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both."

Act § 304(a)(1); 21 U.S.C. 334(a)(1)

"Sec. 304. (a)(1) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or a while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not,

under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States 'or United States court of a territory' within the jurisdiction of which the article is found. . . ."

Act § 505(a); 21 U.S.C. 355(a)

"(a) No person shall introduce or deliver for introduction into interstate commerce, any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

Act § 505(d); 21 U.S.C. 355(d)

"(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect

to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

Act § 505(e); 21 U.S.C. 355(e)

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug, under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of

use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact. . . ."

Act § 505(h); 21 U.S.C. 355(h)

"(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated

by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. . . ."

## Judgment of Court of Appeals.

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 71-1512

CIBA CORPORATION,

Appellant,

vs.

ELLIOTT L. RICHARDSON, Secretary of Health, Education and Welfare and DR. CHARLES C. EDWARDS, Commissioner of Food and Drugs.

(D. C. Civil Action No. 1210-70)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Present: HASTIE, VAN DUSEN and ALDISERT, *Circuit Judges.*

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the District of New Jersey and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said

District Court, filed March 10, 1971, be, and the same is hereby affirmed, with costs taxed against appellant.

ATTEST:

S/ THOMAS F. QUINN
Clerk

June 5, 1972
Certified as a true copy and issued in lieu of a formal mandate on June 27, 1972.

S/ THOMAS F. QUINN
Test: THOMAS F. QUINN
Clerk, United States Court of Appeals For The Third Circuit.

## Opinion of Court of Appeals.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 71-1512

CIBA CORPORATION, a corporation of the State of Delaware,
Appellant,

vs.

ELLIOTT L. RICHARDSON, Secretary of Health, Education & Welfare and DR. CHARLES C. EDWARDS, Commissioner of Food and Drugs.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Argued April 11, 1972

Before: HASTIE, VAN DUSEN and ALDISERT, *Circuit Judges.*

OPINION OF THE COURT

[Filed June 5, 1972]

PER CURIAM:

Ciba Corporation has taken this appeal from an order of the District Court for the District of New Jersey dismissing a complaint in which Ciba sought a declaratory determination that its drug product, Ritonic Capsules, is exempt from the requirement of 1962 amendments of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, that new drugs be excluded from the market unless proven effective as claimed for them. The complaint also sought an injunction against the implementation of an adminis-

trative order, entered by the Commissioner of Food and Drugs after notice and opportunity for an evidentiary hearing, that withdrew approval of the drug upon the basis of a finding that the manufacturer's claims as to its effectiveness were unproven. On appeal, the Court of Appeals for the Second Circuit has affirmed that order. *Ciba-Geigy Corp.* v. *Richardson*, 1971, 446 F.2d 466. That affirmance occurred after the district court had dismissed the present suit and is subject to review by the Supreme Court.

The appellant's basic position seems to be that neither the Commissioner in an administrative proceeding under § 355(e) to determine whether lack of effectiveness as claimed makes a drug unmarketable, nor a court of appeals in reviewing the administrative decision, has jurisdiction to decide as to threshold question whether the product in controversy is a "new drug" within the meaning of the statute, § 355, that covers "new drug" applications and administrative proceedings pursuant thereto. We find no merit in that argument. Inherent in the grant of administrative competency to conduct and decide new drug proceedings is jurisdiction to decide whether the product in question in a given case is lawfully subject to such a proceeding. And, if the administrative agency takes jurisdiction, the same jurisdictional issue is present for judicial review on direct appeal from the administrative decision.

In disapproving Ritonic Capsules the Commissioner and the Court of Appeals for the Second Circuit necessarily decided that the 1962 amendments of the Act were applicable to that product. That determination is reviewable by the Supreme Court. It is neither necessary nor appropriate that the District Court for the District of New Jersey entertain a separate suit by the loser in the administrative proceeding and in the direct appeal therefrom for a redetermination of the same question.

The judgment will be affirmed.

**Opinion of Court of Appeals for the Fourth Circuit in Bentex Pharmaceuticals, Inc. vs. Richardson.**

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

No. 71-1243

BENTEX PHARMACEUTICALS, INC., et al.,

Appellants,

—versus—

ELLIOT L. RICHARDSON, Secretary of the Department of Health, Education and Welfare and CHARLES C. EDWARDS, Commissioner of the Food and Drug Administration,

Appellees.

Appeal from the United States District Court for the District of South Carolina, at Greenville. ROBERT W. HEMPHILL, District Judge.

(Argued December 8, 1971 Decided May 23, 1972.)

Before WINTER, RUSSELL and FIELD, Circuit Judges.

*Opinion of Court of Appeals for the Fourth Circuit in Bentex Pharmaceuticals, Inc. vs. Richardson.*

RUSSELL, Circuit Judge:

This appeal turns on a construction of the Federal Food, Drug and Cosmetic Act of 1938, as amended in 1962,[1] 21 U.S.C. 301, *et seq.* This statute requires pre-marketing approval and clearance of any "new drug" by the Secretary of Health, Education and Welfare.[2] The term "new drug" is defined as one "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *."[3] From

---

[1] There was an earlier Food and Drug Act of 1906. 34 Stat. 768 (1906). It did not provide for any pre-marketing review of the safety of drugs. The sulfanilamide episode in 1938 prompted the enactment of the Federal Food, Drug and Cosmetic Act of that year to replace the earlier Act and to provide, *inter alia*, for such pre-marketing review of "new drugs". See C. W. Dunn *Federal Food, Drug and Cosmetic Act—A Statement of Its Legislative Record*, pp. 1316-27 (1938). The fears generated by the thalidomide tragedies gave the impetus for the Amendments of 1962. See Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 Georgetown Law Journal, 185 at p. 191, n. 45 (1971).

[2] Section 355(a), 21 U.S.C.

The actual approval of a "new drug" under the Act is normally processed by the Food and Drug Administration (FDA) in the Department of Health, Education and Welfare (HEW), and the approvals, when granted, are generally referred to as New Drug Approvals (NDAs). FDA, when used herein, refers to the Food and Drug Administration, and NDA is intended to describe an approval by FDA of a "new drug" application under the Act.

[3] Section 321 (p)(1), 21 U.S.C.

See, also, *United States* v. *Articles of Drug Labeled "Quick-O-Ver"* (D.C.Md. 1967) 274 F. Supp. 443, 445, n. 2:

> "The statutory definition of the phrase 'new drug' controls this case, regardless of any other meaning attributable to the phrase or to the word 'new' by common understanding or other authority."

a denial of a pre-marketing approval or a withdrawal of a previously given approval, an appeal, originally to the District Court, now to the Circuit Court of Appeals, is authorized.[4] Drugs, which do not fit the definition of a "new drug" do not require FDA clearance for marketing. There is no provision in the Act for administrative determination whether a particular drug is a "new drug" nor for any right of appeal from any such determination. The FDA sometimes offers to render "informal advice" as to whether it considers a product a "new drug" but it uniformly designates such opinion "advice".[5] Accordingly, the responsibility for determining whether its product is a "new drug", requiring pre-marketing clearance by FDA, rests on the manufacturer, who must act at its peril.[6] If it makes an incorrect determination and seeks to market without FDA clearance a drug meeting the definition of a "new drug", it lays itself open to drastic judicial procedures that may be invoked by FDA, i.e.: The product may be seized in an *in rem* action instituted by the Government;[7] its sale may be enjoined in an action begun by the Government;[8] in addition, the manufacturer may be subjected to criminal action.[9] All these remedies must be prosecuted

---

[4] Section 355(h), 21 U.S.C.

[5] 21 C.F.R. 130.39.

[6] Cf. *United States* v. *Dotterweich* (1943), 320 U. S. 277, 281, where, speaking of the Act of 1938, the Court said:

"In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."

[7] Section 334, 21 U.S.C.

[8] Section 332, 21 U.S.C.

[9] Section 333, 21 U.S.C.

in the District Court and the role of the Secretary is that of plaintiff or prosecutor. The Act thus establishes two forums for the regulation of drugs: One is administrative and deals with the procedures for securing pre-marketing clearances for the statutorily defined "new drug", with right of appeal from a denial of approval, or withdrawal of a previous approval, to the District Court, later changed to the Court of Appeals; the other is judicial and is intended to make effective and give strength to the requirement that "new drugs" be cleared as safe before marketing by providing the Government with certain potent judicial remedies, *available exclusively in the District Court.*

Under the 1938 Act, a new drug was one "not generally recognized by experts * * * as safe for its intended use." The Amendments added "effectiveness" as well as "safety" to the definition. Simply stated, the change effected by the Amendments was that, whereas prior to the 1962 Amendments a drug which was generally recognized as safe was not a "new drug", the Amendments defined a drug as "new" if it were not generally recognized as both safe *and effective.* Furthermore, they replaced the provision for automatic approvals of applications not disapproved within a fixed time with a requirement of a positive act of approval on the part of FDA.[10] They proceeded to provide that the Secretary must find as a basis for clearance of a new drug not only safety but "substantial evidence" of effectiveness, "consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved."

---

[10] Section 355(c), 21 U.S.C.

The applicability of these amendments, including the revised definition of "new drug" to drugs already marketed, either under previously issued NDAs, or as "old drugs" requiring no FDA approval, was carefully spelt out in the Amendments and certain "grandfather rights" were granted. For all previously NDA'd drugs, the Amendments conferred a grace period of two years after the effective date of the Amendments within which to prepare evidence to satisfy the new requirement of efficacy added by the revised definition of "new drug"; during that "transitional" period no revocation or withdrawal of approval because of a lack of substantial evidence of efficacy of such drugs was permitted.[11] For a drug, however, which on the day prior to the enactment of the Amendments was (1) being "commercially used or sold in the United States," (2) "was not a new drug as defined by" the pre-Amendment statute and (3) "was not covered by an effective new drug application, * * *" "on the day immediately preceding the enactment date" of the Amendments, there was a permanent exemption from the efficacy provisions of the Amendments so long as the drug's labeling remained the same.[12] In summary, these provisions required that, "Those drugs which had obtained effective NDAs must be proven efficacious after two years; those

---

[11] Section 107(c)(3), P.L. 87-781, Section 321, Supplement 1972, 21 U.S.C.

[12] Section 107(3)(4), P.L. 871-781, Section 321, 1972 Supplement, 21 U.S.C.; see, also, *Tyler Pharmacal Distrib. Inc.* v. *U.S. Dept.* v. *Health, E. & W.* (7th Cir. 1969), 408 F.2d 95, 99.

It should be noted that Section 321(p)(1) provides a "grandfather clause" applicable to pre-1938 drugs. This clause is not relevant to this action, which is concerned with drugs introduced between 1938 and 1962, and the subsequent references to "grandfather clause" in this opinion are to section 107(c)(4).

which had not need never be proven efficacious so long as they had become safe prior to the 1962 Amendments.'"[13]

The "grandfather clause" set forth in Section 107(c)(4) simply continues for the products satisfying its criteria the pre-1962 definition of a "new drug". Its effect is to assure that a drug which was generally recognized by qualified experts as safe for the purposes recommended for its use on October 9, 1962, need not be NDA'd as *effective* under the new requirements for the issuance of an NDA as a "new drug". But any drug, whether requiring an NDA or not, whether a "new drug" or an "old drug", is subject to the misbranding provisions of the Act and may be proceeded against on that basis. A false claim of either safety or effectiveness constitutes misbranding, rendering a drug subject to both civil and criminal penalties. *United States* v. *Article of Drug Labeled Decholin*

---

[13] Note, *Drug efficacy and the 1962 Drug Amendments*, 60 Georgetown Law Journal, p. 196 (1971).

See, also, *United States* v. *Allan Drug Corp.* (10th Cir. 1966) 357 F. 2d 712, 719, note 9, quoting from the Supplemental Report of the Senate Committee on Drug Amendments of 1962, as set forth in the notes to Section 321, 21 U.S.C.:

> "Thirdly, in the case of a drug on the market which was never subject to the new-drug procedure before, the amendments to the new drug definition relating to drug effectiveness would not apply to existing labeling claims."

In the Conference Report of the House Managers on the Amendments, it was stated that the Amendments included "the Senate language providing with respect to existing label claims of drugs that have never previously been subject to the new-drug procedure substantially the same savings provisions as the corresponding provision of the House bill (Section 197(d))." *U. S. Code Congressional and Adminstrative News*, 87th Congress, 2d Session (1962), p. 2932. Again, in H.R. Rep. #2526, p. 23, it is stated that the exemption granted by the "grandfather clause" applies "to existing claims of drugs that have never been subject to the new-drug procedure".

(D.C. Mich. 1967), 264 F. Supp. 473, 482-3; *United States* v. *Lanpar Company* (D.C. Tex. 1968), 293 F. Supp. 147, 153-4.[14] Accordingly, in *United States* v. *Guardian Chemical Corporation* (2d Cir. 1969), 410 F. 2d 157, a drug manufacturer was acquitted of a charge of marketing a "new drug" without securing an NDA, but was convicted under a separate count of the indictment charging misbranding. "Thus", as one commentator has aptly stated, "the amplications of the FDA's authority (as granted by the 1962 Amendments) is (was) not due to the absence of power to proceed against ineffective drugs, but rather to authorize the exercise of that power at the initial stage, that is, *before* marketing, and also to shift the burden of proof to the applicant." Jurow, *The Effect on the Pharmaceutical Industry of the "Effectiveness" Provisions of the 1962 Drug Amendments,* 19 Food, Drug, Cosmetic Law Journal, 110, at p. 116 (1964).[15]

---

[14] See, also, *Pfizer, Inc.* v. *Richardson* (2d Cir. 1970), 434 F. 2d 536, 548:

"A good case could certainly be made that, quite apart from this, the 'efficacy' of a drug is necessarily related to the use recommended."

[15] See, also, Senate Report #1744, *U. S. Code Congressional and Administrative News,* 87th Cong., 2d Sess. (1962), pp. 2892 and 2893, where, in justifying the Amendments, it is stated:

"• • • where a drug is essentially innocuous, it (FDA) must clear the drug despite the fact that its claim of effectiveness is not borne out by the evidence. In such cases the Food and Drug Administration may proceed against the drug manufacturer by seizure of the drug for misbranding. However, the Department believes that the manufacturer should satisfy the Food and Drug Administration that his product is effective for the purposes claimed before it is marketed. • • • No question of safety is involved, and the Food and Drug Administration presently has ample power, including seizure, to proceed against any safe drug for which unsupported claims of effectiveness are made."

*Opinion of Court of Appeals for the Fourth Circuit in Bentex Pharmaceuticals, Inc. vs. Richardson.*

The plaintiffs, manufacturers of a prescription drug containing pentylenetetrazol and nicotinic acid, claim the protection of the "grandfather clause" included in Section 107(c)(4) for their products and that contention represents the substantive issue in this case. It is undisputed that plaintiffs had marketed their product commercially for many years prior to and on October 9, 1962,[16] without an NDA under the claim that it was not a "new drug" within the definition of the Act, and therefore required no NDA. Such claim was supported, it is asserted, both by previous informal advice of the Secretary and by the general recognition of the safety of such product by "experts qualified by scientific training and experience" to make such evaluation. The defendants, the Secretary of HEW and the Commissioner of Food and Drugs, in their brief, concede that "Over the years since 1938" and until 1968, the Food and Drug Administration had given the opinion that certain pentylenetetrazol combinations similar to those of the appellant were not "new drugs."[17] Moreover, the District Court observed in its opinion that there was "no contention (by the FDA) that the use of the plaintiffs' drugs in treatment of the symptoms of senility in geriatric patients is in any way harmful to them, either directly or indirectly by

---

[16] This was the day "immediately preceding the enactment date" of the Amendments of 1962.

[17] It is, of course, axiomatic that such opinions or advice can create no estoppel against the Government. *AMP Incorporated* v. *Gardner* (D.C.N.Y. 1967), 275 F. Supp. 410, 412, n. 1, aff. 389 F. 2d 825, cert. den. 393 U. S. 825, reh. den. 395 U. S. 917. The most that can be claimed for such opinions is that they lend color and good faith to the plaintiffs' claims. FDA not only has the right but is obligated to change its opinion if it learns its prior position was erroneous. *United States* v. *60 28—Capsule Bottles, More or Less, etc.* (D.C.N.J. 1962) 211 F. Supp. 207 , 215, aff. 325 F. 2d 513.

causing disuse of better drugs." On this basis, the plaintiffs contended that they met exactly the criteria established for exemption from the requirements of general recognition by qualified experts of the effectiveness of their products as provided in the permanent grandfather section of the 1962 Amendments.

Prior to the filing of this action, however, the defendants withdrew their advice that products such as those distributed by the plaintiffs were "old drugs" and contended that such products did not qualify for exemption under the "grandfather clause", Section 107(c)(4). The basis for this contention was the claim (1) that these drugs were not generally recognized by qualified experts as safe as of the effective date of the Amendments of 1962 and (2) that they were "me-too" drugs, whose marketability without FDA clearance depended in turn on the NDAs granted the basic drug, and for that reason must be regarded as drugs covered by an effective NDA on the effective date of the Amendments.[18] Faced with this threat, the plaintiffs began

---

[18] The defendants assert that three "new drug" applications filed by other manufacturers and earlier approved by the FDA covered drugs similar in every particular to those marketed by the plaintiffs. Proceedings for withdrawal of the approval of such "new drugs" had been begun by FDA in advance of the filing of this action. In fact, such proceedings to a large extent prompted this action. It is the contention of the defendants that the withdrawal of what they describe as "the primary NDAs" operates to remove the marketability from what they assert are the "me-toos" or non-NDA'd drugs which are similar to other drugs which have secured effective NDAs. The plaintiffs deny that their drugs are like those previously NDA'd. They argue that those NDA'd products, unlike theirs, are intravenously administered or are a compound containing, in addition to the components of plaintiffs' drugs, reserpine. Such changes in formula or method of administering vitiated any claim by their manufacturers that they were marketing an old drug and required an approval as a new drug.

(*footnote continued on following page*)

this action for a declaratory judgment sustaining their right to exemption from proof of the effectiveness of their product and for injunctive relief awaiting the disposition of their claim for exemption. The defendants directed against the complaint a motion to dismiss or for summary judgment, which, in essence, (1) asserted primary jurisdiction in the Secretary to determine whether the products of the plaintiffs met the requirements for exemption under Section 107(c)(4), particularly whether they were "new drugs", requiring pre-marketing approval under the Act, (2) denied the propriety of a declaratory judgment action, and (3) claimed that the products of the plaintiffs were "new drugs" which did not qualify for exemption under the "grandfather clause".

The District Court sustained the right of the plaintiffs to maintain a suit for a declaratory judgment and the jurisdiction of the Court in such action to determine judicially whether the products of the plaintiffs were "new drugs", on the effective date of the Amendments, and whether they were or were not entitled to the benefits of

---

(*footnote continued from preceding page*)

The plaintiffs assert their drugs are not subject to any such disability. These, however, are questions of fact not relevant to the simple questions of jurisdiction presented by this appeal and may be inquired into on remand. Even if the products of the plaintiffs be deemed "me-too" drugs (i.e., simply "a copy of a pioneer drug which preceded it on the market"), it is by no means clear that they do not "meet the requirements for section 107(c)(4) protection" and the argument of the Government to the contrary has been described as "lacking in merit." See, Note, *Drug Efficacy and the 1962 Amendments*, 60 Georgetown Law Journal, 185 at pp. 203-207 (1971); *Hagan, Grandfather Protection under the Drug Amendments of 1962*, 19 Food Drug Cosmetic Law Journal, 119, at p. 125 (1964).

the "grandfather clause".[19] However,—and this is the nub of the controversy between the parties on this appeal—it concluded that the Secretary had concurrent jurisdiction to determine whether plaintiffs' products were "new drugs", requiring pre-marketing clearance, and that, because of the greater expertise of the Secretary in the field, it deferred to the Secretary's assumed jurisdiction to determine whether the drugs of the plaintiffs came within the exemption provided by the "grandfather clause". It enjoined any action against the plaintiffs and their products until the plaintiffs had been accorded a hearing before the Secretary on the issue of the qualifications of these drugs for protection under the "grandfather clause". It is the conclusion of concurrent jurisdiction in the Secretary and deference to that assumed concurrent jurisdiction from which the plaintiffs have prosecuted this appeal.

The defendants, on the other hand, have not cross-appealed and have accordingly acquiesced in the decision of the District Court that the action is properly maintainable as a declaratory judgment proceeding under Section 2201, 28 U.S.C. and that the District Court has jurisdiction over the substantive issue in this case, i.e., whether plain-

---

[19] In support of the right of the plaintiffs to maintain a suit for declaratory judgment, the District Court relied on *Abbott Laboratories* v. *Gardner* (1967), 387 U. S. 136 and the companion case of *Toilet Goods Assn.* v. *Gardner* (1967), 387 U. S. 158. Additional support for such right is found in *AMP, Incorporated* v. *Gardner, supra; Durovic* v. *Richardson* (D.C. Ill. 1971), 327 F. Supp. 386; *Lemmon Pharmacal Co.* v. *Richardson* (D.C. Pa. 1970), 319 F. Supp. 375. The right of the Court to determine the applicability of the "grandfather clause" is equally clear and has been sustained in *United States* v. *Articles of Drug Labeled "Quick-O-Ver"* (D.C. Md. 1967), 274 F. Supp. 443, 445; and *United States* v. *Article Consisting of 36 Boxes, etc.* (D.C. Del. 1968), 284 F.Supp. 107, 112, n. 13, aff. 415 F.2d 369.

tiffs' products are "new drugs", as defined in the Act. The question in the case is thus whether the Secretary has concurrent jurisdiction to determine whether a drug is a "new drug" under the Act or whether that issue is cognizable only in the District Court. Contrary to the conclusion of the District Court, we conclude that the Act confers no such jurisdiction on the Secretary and, therefore, no basis for any deference by that Court to the concurrent jurisdiction of the Secretary.

The FDA has neither primary jurisdiction, as the defendants argue, nor concurrent jurisdiction, as the District Court concluded, to adjudicate whether a product is an old or a new drug. It may, in its prosecutorial role, reach a conclusion that a product being marketed is a "new drug" requiring pre-marketing approval; but that opinion is not adjudicatory, it is only the basis on which the FDA, as the prosecutor or iniator of either a seizure or injunctive action in the District Court, may invoke the jurisdiction of that Court to determine, among other issues, whether the drug challenged is a "new drug". There is manifestly no provision in the Act for an administrative proceeding before the Secretary to compel the filing of a "new drug" application or to halt the marketing of a drug for which there is no approval by the Secretary. It is not without significance that, so far as the official reports reflect, the Secretary has never attempted directly to exercise such jurisdiction. The only occasions on which he has sought to assert such jurisdiction has been as an element in his defense to a declaratory judgment action.[20] Moreover, when FDA undertook its new responsibilities under the

---

[20] See, *Hynson, Westcott & Dunning, Inc.* v. *Richardson* (Civ. No. 21112, D. Md., decided 9/16/70); and *Ciba Corp.* v. *Richardson* (Civ. No. 1210-70, D. N.J., decided 3/10/71); but cf., *Lemmon Pharmacal, supra.*

1962 Amendments, it sought merely to review "the efficacy of *all new drugs that had been cleared,* for safety only, between 1938 and October 10, 1962" (Italics added) and enlisted the services of the National Academy of Sciences-National Research Council for this limited task. It did not assert the right to review, or assume the burden of reviewing, for efficacy, drugs such as those involved here, which had been commercially marketed on the basis of a general recognition of safety without an effective NDA as of the effective date of the 1962 Amendments. It, thus, recognized that its adjudicatory rights extended merely to the approval, or the withdrawal of approval,[22] of a drug embraced in a "new drug" application that had been approved. This confirms the conclusion that the halting of the marketing of a drug, for which there is no NDA, may not be by administrative action but must be by an injunction or *in rem* seizure proceeding, in which the Secretary appears, not in a judicial but in a prosecutorial role.[23] Those are the procedures prescribed and available to the Government under the Act.[24] The Secretary, it is true, has offered to provide

---

[21] See *Pfizer, Inc.* v. *Richardson* (2d Cir. 1970), 434 F.2d 536, 539, and 31 F.R. 9426.

[22] The authority of the Secretary to withdraw an approval of any "new drug" application filed under the Act of 1938 after hearing is specifically granted by Section 355(e), 21 U.S.C.

[23] Of course, in a proper case the Government may also institute criminal proceedings in the District Court. See Section 333, 21 U.S.C.

[24] Cf. *United States* v. *Allan Drug Corporation* (10th Cir. 1966), 357 F.2d 713, 718, cert. den. 385 U. S. 899, in which the Secretary is quoted to the effect that, "'As to drugs already on the market that have never been subject to the new-drug procedure but are not generally recognized as effective, the burden remains on the Government to prove *in court,* insofar as unchanged labeling claims are concerned, they do not have their claimed effect. If the labeling claims are changed, however, these must be approved under the new-drug procedure.'" (Italics added.)

"advice" on whether a product meets the qualification of an old drug but he categorizes his action in such instances as merely "advice" and makes no claim of finality therefor. Nor is there, as we have already observed, any provision for judicial review of such "advice".[25] The only adjudicatory right vested by the Act in the Secretary relates to approval, or withdrawal of an approval, of a "new drug" application.[26] That this is so follows from the limitations placed by the Act on judicial review of the decisions of the Secretary. The Secretary himself asserted, shortly after the enactment of the 1962 Amendments, in *Turkel* v. *Food and Drug Administration, Dept. of H.E.W., supra,* at p. 845, that the Act "grants a right to appeal only from an order of the Food and Drug Administration approving or disapproving a New Drug Application". In keeping with the Secretary's contention as to the extent of his adjudicatory powers, the Court in that case held that the right of appeal from an order of the Secretary "applies only to an order of the Secretary refusing or withdrawing approval of an application for sale and distribution of a new drug" (at pp. 845-6). It is not to be assumed that the Act confers an adjudicatory right on the Secretary from which no judicial review, however limited, is provided or allowed. Yet this is the unusual situation that would be presented if the Secretary were held to have jurisdiction to adjudicate whether a drug meets the statutory criteria of a "new drug".[27]

---

[25] See *Turkel* v. *Food and Drug Administration, Dept. of H.E.W.* (6th Cir. 1964), 334 F.2d 844, 846, cert. denied 379 U. S. 990, rehearing denied 380 U.S. 927: "The jurisdiction of the United States Courts of Appeal to review administrative acts of federal agencies is wholly dependent upon statute."

[26] Section 355(b), 21 U.S.C.

[27] Cf., *Abbott Laboratories* v. *Gardner* (1967), 387 U. S. 136, at p. 140.

*Opinion of Court of Appeals for the Fourth Circuit in Bentex Pharmaceuticals, Inc. vs. Richardson.*

The District Court, in finding concurrent jurisdiction, held that "This grant of authority to approve or withhold approval of new drug application, * * * necessarily implies authority for F.D.A. to determine the threshold question of whether the article involved is a drug which required an approved new drug application for lawful interstate shipment." This reasoning assumes that an application for approval by the Secretary under the Act poses as its initial issue whether the product is a new drug. No such issue is posed by the application. The very filing of the application is a concession and recognition by the applicant-manufacturer that the article is a "new drug"; otherwise, there would be no reason to file the application. As a matter of fact, in the prescribed form of application, the applicant describes his product as "a new drug". 21 C.F.R. 130.4. The applicant makes the determination whether his product is a "new drug" and whether he must file for pre-marketing clearance by the Secretary. And when filed, the application puts in issue only one question: Is the article safe and effective? That and that alone is the issue to be considered by the Secretary in connection with an application for approval filed by a manufacturer under Section 355(d), 21 U.S.C. That issue is quite different from that presented when there is an issue whether a drug fits the statutory definition of "new drug" in the Act. The criterion for ascertaining whether a product is within the statutory definition of "new drug" under the Act is not safety and effectiveness *per se,* which, as we have observed, is the issue before the Secretary in connection with application for approval of a "new drug", but "whether the government has shown by a preponderance of the evidence that the 'drug' is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recom-

mended or suggested in the labeling thereof."[28] That is an issue that must be and is resolved, sometimes with, and at other times without a jury, in practically every injunctive, seizure, or criminal proceeding under the Act. See, for instance, *United States* v. *Articles of Drug Labeled "Quick-O-Ver", supra; United States* v. *41 Cases, More or Less* (5th Cir. 1970) 420 F.2d 1126, 1128; *United States* v. *Article of Drug, etc., supra,* at p. 392; *United States* v. *Article . . . Consist. of 216 Carton* (2d Cir. 1969), 409 F.2d 734, 742; *United States* v. *Article Consisting of 36 Boxes, etc., supra,* at p. 113; see, also, *United States* v. *Article of Drug, etc.* (D.C. Md. 1971), 331 F. Supp. 912, 915-7. That was one of the issues resolved in the declaratory action of *Lemmon Pharmacal Co.* v. *Richardson, supra.*[29] It is mani-

---

[28] *United States* v. *Articles of Drug Labeled "Quick-O-Ver", supra,* at pp. 445-6.

See, also:

*AMP, Incorporated* v. *Gardner, supra,* at p. 831:

"But the safety of the products is not what is at issue here. The question is whether there is general recognition among qualified experts of the products' safety and effectiveness—if there is not, the products must be submitted to the Secretary of Health, Education and Welfare for a determination as to safety, adequacy of testing, etc."

*United States* v. *Article of Drug, etc.* (5th Cir. 1969), 415 F.2d 390, 392:

"Both sides agree that the nature of expert opinion about Furestrol, and not its actual safety or effectiveness, is the ultimate fact issue."

Cf. *United States* v. *Seven Cartons, More or Less, etc.* (7th Cir. 1970), 424 F.2d 1364, 1365.

[29] In discussing this case, the commentator in 60 Georgetown Law Journal, p. 199, note 87, says:

"In *Lemmon Pharmacal,* the Court, while noting that determining safety and efficacy would normally be within the primary jurisdiction of the agency, concluded that the question of section 107(c)(4) protection was properly before it."

festly a justiciable issue and the plaintiffs are entitled to a judgment on that issue by the Court, which alone has the jurisdiction to resolve it. In the absence of any statutory review proceedings within which they may assert their claim of exemption, the plaintiffs are not to be compelled to proceed at their peril, subject to the possibility of both civil and criminal penalties, but are entitled to seek relief by way of a declaratory judgment action. The District Court should accordingly have retained jurisdiction and proceeded to determine whether the plaintiffs' drugs met the criteria for exemption under Section 107 (c) (4). We deem it premature for us to consider at this stage, whether plaintiffs' products meet such criteria. That issue was not developed in the record before, or ruled on by, the District Court.[30] Upon remand, the issue can be considered by the Court in the light of the record that may be made by the parties.

REMANDED, WITH DIRECTIONS.

---

[30] See *United States* v. *Article Consisting of 36 Boxes etc.*, *supra*, at p. 113.